

Upon entry of this Amendment, claims 1-10 and 59-74 will be pending in the application, claims 11-58 having been cancelled without prejudice in view of the restriction requirement.

Applicant has added new claims 59-74. These amendments are supported in the specification, for example, at paragraph 0038. Approval and entry are requested.

### **ELECTION/RESTRICTIONS**

Applicant hereby affirms the election of Group I, which includes claims 1-10. Non-elected claims 11-58 have been cancelled in the attachment hereto without prejudice or disclaimer to their reintroduction in continuation, continuation-in-part, and/or divisional application(s).

### **CLAIM REJECTIONS – 35 U.S.C. § 102**

Claims 1-10 have been rejected under 35 U.S.C. § 102(b) (hereinafter “Section 102(b)”) as being anticipated by U.S. Patent No. 5,880,117 to Arnold (hereinafter “Arnold”) and U.S. Patent No. 5,578,588 to Mattern et al. (hereinafter “Mattern”).

It is fundamental law that a reference, to anticipate a claim under Section 102(b), must fully disclose the invention as claimed, and thus each limitation of the claimed invention must be identically disclosed in the reference. *See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986). Anticipation must be found in a single reference. *See, e.g., Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 726-27, 220 U.S.P.Q. 841 (Fed. Cir. 1984). The absence of any element of the claim from the cited

reference negates anticipation under Section 102(b). *See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 U.S.P.Q. 1264 (Fed. Cir. 1984).

Because Arnold and Mattern each fail to meet this burden of anticipation under Section 102(b), these rejections are respectfully traversed.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of anticipation against independent claim 1 of the present application, for example, because Arnold and Mattern fail to disclose, expressly or inherently, a compound for increasing the concentration of a parent androgen in a subject in vivo, wherein the parent androgen has a skeletal structure including a 4 position and a 17 position and the parent androgen further has a 17 $\beta$ -hydroxy group comprising a 17 $\beta$ -hydroxy oxygen appended to the 17 position and a 17 $\beta$ -hydroxy hydrogen appended to the 17 $\beta$ -hydroxy oxygen, wherein the compound comprises a substrate having the skeletal structure of the parent androgen comprising a 4 position and a 17 position corresponding to the 4 and 17 positions respectively of the parent androgen, wherein the substrate comprises a carbon-carbon double bond at the 4 position, wherein the skeletal structure of the parent androgen embodied in the substrate is selected from the group consisting of androst-4-ene-3 $\alpha$ ,17 $\beta$ -diol, androst-4-ene-3 $\beta$ ,17 $\beta$ -diol, and mixtures thereof, and wherein a promoiety is appended to the 17 $\beta$ -hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen, the promoiety comprising an alkylcarbonate ester, as disclosed in claim 1.

Arnold and Mattern disclose the testosterone precursors 4-androstenediol and androstenedione, respectively. Neither of these compounds comprises an alkylcarbonate ester promoiety appended at the 17-position. The 4-androstenediol compound disclosed in Arnold has a hydroxyl group at the 17-position, and the androstenedione compound disclosed in Mattern has a ketone at the 17-position.

Based on statements made by the Examiner in the Office Action and during the personal interview of March 12, 2003, it appears that the Examiner has construed claims 1-10 as reading on any compound having the skeletal structure of a parent androgen or capable of increasing the concentration of a parent androgen *in vivo*. Applicant respectfully submits that in so construing the claims, the Examiner has impermissibly neglected to take into consideration the recitation of the claimed "promoiety comprising an alkylcarbonate ester," as recited in claim 1. Each limitation of a claim is deemed material to defining the scope of an invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). This language therefore may not be simply disregarded.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102(b) rejections of claim 1 over Arnold and Mattern.

Applicant further respectfully submits that claims 2-10, being dependent from claim 1 and including all of the distinguishing features thereof, also are patentable over Arnold and Mattern for the reasons advanced above.

The Examiner also rejected claims 4 and 6 under 35 U.S.C. 102(b) based upon a public use or sale of the invention, and more particularly based upon the

alleged manufacture of 4-androstenediol ethyl carbonate by Taizhou Xingye Chemical Factory on December 29, 2001.

Applicant respectfully traverses this rejection.

Section 102(b) states as follows:

a “person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country or *in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.*”

(Emphasis added.)

The document cited by the examiner does not constitute a public use or sale, nor on its face does it necessarily even implicate one. The document alone does not constitute evidence demonstrating that a public use or sale occurred, and does not provide a proper basis for a *prima facie* case of anticipation under Section 102(b).

Even if the document had reflected a public use or sale, which it does not, the document still would not provide a proper ground for a Section 102(b) rejection, for example, because any such manufacture would not have occurred “more than one year prior to the date of the application for patent in the United States.” The alleged manufacture date is less than one month before the filing date of this application. Further, the document does not disclose that the alleged public use or sale occurred “in this country.”

For these reasons, Applicant respectfully requests that the Section 102(b) rejection of claims 4 and 6 be withdrawn.

## CLAIM REJECTIONS – 35 U.S.C. § 112

Claims 1-10 have been rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the use of the terms “comprising” and “including” in claim 1 render the claims indefinite. According to the Examiner, the use of the term “comprising” is indefinite because it “is inclusive and fails to exclude unrecited steps” and “leaves the claim open for inclusion of unspecified ingredients even in major amounts.” The term “including” was rejected on similar grounds, inasmuch as the Examiner has argued that it “may include elements other than those recited in the claims.”

Applicant respectfully traverses this ground of rejection.

Applicant agrees that the terms “comprising” and “including” constitute “open” language and allow for the inclusion of additional elements other than those recited in the claims. But the use of either or both of these terms in the instant claims, and in chemical claims in general, does not render the claims indefinite. It is axiomatic that the terms “comprising” and “including” are standard transition phrases ubiquitously recited in most patents. *See, e.g.*, MPEP § 2111.03.

The Examiner has not advanced any rationale as to why the claims must be “closed” rather than “open” with regard to its claimed limitations. For example, claim 1 recites (in summary form) a compound “comprising” (a) a substrate and (b) a promoiety appended to the 17 $\beta$ -hydroxy oxygen of the substrate. Claim 1 remains open, however, to additional elements, such as, by way of example, a second alkylcarbonate ester appended to the 3-hydroxyl oxygen of the substrate. *See, e.g.*, claim 5 reciting that the “compound comprises androst-4-ene-3,17 $\beta$ -diol 3,17-

di(alkylcarbonate).

Similarly, claim 1 recites that the compound is capable of increasing the concentration of a parent androgen "having a skeletal structure including a 4 position and a 17 position." As explained, for example, in numbered paragraph 0034 of the specification, the numbering used in the present application corresponds to the ring identification and carbon numbering system well known in the field of steroid chemistry, for example, as adopted in the 1989 recommendations of the International Union of Pure and Applied Chemistry ("IUPAC"). Those of ordinary skill in the art would have understood that the androgen compounds have an accepted carbon numbering system, and that the accepted carbon numbering system *includes* a 4-position and a 17-position. The accepted carbon numbering system is not closed to a 4-position and a 17-position; instead, androgen compounds include other numbered carbon positions, *e.g.*, a 1-position, 2-position, 3-position, 5-position, etc. Applicant respectfully submits that the use of open language in claim 1 to recite the 4 and 17-positions is more concise and appropriate than the closed language proposed by the Examiner.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection under Section 112.

Claims 1, 2, 5-7, 9, and 10 have been rejected under 35 U.S.C. § 112, first paragraph, on the following ground:

The specification, while being enabling for androst-4-ene-3,17- $\beta$ -diol 17- $\beta$ -alkyl carbonates, does not reasonably provide enablement for every compound having 4 and 17 position[s] in the structure.

See Office Action, page 4.

Applicant respectfully traverses this ground of rejection.

Applicant respectfully submits that the Examiner has not fully considered the language of the claims reading each claim as a whole, as is required. Claim 1 recites (in summary form) a “compound ... comprising ... a substrate having the skeletal structure of the parent androgen..., the skeletal structure of the parent androgen *embodied in the substrate* being selected from the group consisting of androst-4-ene-3 $\alpha$ ,17 $\beta$ -diol, androst-4-ene-3 $\beta$ ,17 $\beta$ -diol, and mixtures thereof ....” The Examiner has acknowledged that the specification enables these particular structures. Contrary to the Examiner’s position, claim 1 is not intended to and does not read on “every compound having 4 and 17 position[s] in [its] structure.”

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 112, first paragraph rejection.

Applicant respectfully submits that all claims are in full compliance with Section 112, first and second paragraphs.

#### **CLAIM REJECTIONS – 35 U.S.C. § 103**

In the Office Action, claims 1-10 have been rejected under 35 U.S.C. § 103(a) (hereinafter “Section 103(a)”) as being unpatentable over Arnold and Mattern.

It is fundamental law that it is improper under Section 103(a) to use hindsight reconstruction to pick and choose among isolated disclosure in the prior art to deprecate the claimed invention. *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir.

1992). Teachings of references can be combined only if there is some suggestion or motivation to do so. *Smithkline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 886-87 (Fed. Cir. 1988). This burden of obviousness has not been met with regard to claims 1-10 and, therefore, this rejection is traversed.

Applicant respectfully submits that the Examiner's application of the *Graham* test is in error. The Examiner summarizes step 2 of the *Graham* test as follows:

**2. Ascertaining the differences between the prior art and the claims at issue.**

Instant claims differ from the prior art in claiming a broader scope by claiming "androgen" where as prior art teach[es] testosterone precursors. Testosterone is an androgen.

*See* Office Action, page 6.

Applicant respectfully submits that the Examiner has overlooked one of the limitations of claim 1, giving no patentable weight to the claimed "promoiety comprising an alkylcarbonate ester," as recited in claim 1.

The 4-androstenediol and androstenedione compounds respectively disclosed in the Arnold and Mattern do not contain a promoiety comprising an alkylcarbonate ester. Moreover, neither Arnold nor Mattern, when taken alone in or combination, reasonably suggests modifying their respective compounds to include an alkylcarbonate ester promoiety at the 17-position. Applicant can find no mention at all of an alkylcarbonate ester promoiety at any position in either of these documents.



For these reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 103(a) rejection of claim 1 and claims 2-10, which depend therefrom.

If there are any other fees due in connection with this application, please charge the fees to our Deposit Account No. 501324.

Dated: March 18, 2003

Respectfully submitted,



Stephen T. Sullivan  
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**CERTIFICATE OF EXPRESS MAILING**

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Date of Deposit: March 18, 2003

I hereby certify that this Amendment and Response to Office Action 1 is being deposited with the U.S.

Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, U.S. Patent and Trademark Office, Washington, D.C. 20231.

